

## **REMARKS**

Please amend claims 1, 25, 44, and 60 as indicated in the listing of claims. Claims 79-86 are newly added. Please cancel claims 20-24 without prejudice or disclaimer. Claims 1-4, 16, 19, 25, 28, 29, 31-37, 39-43, 48-52, 55-57, 59-61, 76, 78-86 are pending and at issue. These amendments and additions add no new matter as the claim language is fully supported by the specification and original claims.

### **I. Amendment to the Claims**

Claims 1, 25, 44, and 60 have been amended to include the limitation of a primer with SEQ ID NO: 3 in the first amplification product, which the Examiner found to be free of the art. The claims were also amended to clarify the claims and remove references to the other primers and remove references to PKD1 homologs. Claim 25 has also been amended to clarify that the presence of a mutation is indicative of a PKD1-associated disorder. Claims 20-24 have been cancelled. Claims 79-82 are newly added dependent claims, and list the primers that were removed from the independent claims.

No new matter has been added.

### **II. Antecedent Basis for Deletion of Position 3336 of SEQ ID NO. 1**

The Examiner stated that the specification does not appear to discuss or mention a deletion in SEQ ID. NO.:1 at position 3336, and therefore the specification does not provide proper antecedent basis for the claimed subject matter. (Office Action, page 3.)

Applicants respectfully disagree. The deletion in SEQ ID. NO.:1 is provided for at several places in the specification. In particular, “an oligonucleotide comprising at least ten contiguous nucleotides of SEQ ID NO.: 1, including...a position corresponding to nucleotide 3336, wherein nucleotide 3336 is deleted” can be found in paragraph [0033]. Additionally, paragraphs [0057] and [0117] reads “sequences substantially as set forth in SEQ ID NO.:1...a position corresponding to nucleotide 3336, wherein nucleotide 3336 is deleted.” Also, paragraph

[0146] reads “the mutation comprises SEQ ID NO.:1...nucleotide 3336 is deleted.” Therefore, the specification provides proper antecedent basis for the deletion of nucleotide 3336 in SEQ ID. NO.: 1.

### **III. Rejections under 35 U.S.C. §112, Second Paragraph**

The following claims are rejected for allegedly failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully traverse these rejections as they apply to the pending claims and for the reasons below.

#### **A. Rejection of claims 1-4, 16 and 19**

According to the Office Action, “claims 1-4, 16 and 19 are indefinite because the claim appears to [allegedly] require that the eight primers “selectively hybridize to a flanking sequence... of each of polycystic kidney disease-associated protein-1 (PKD1) gene sequences” and it is not clear if the claimed set must contain primers that hybridize to each possible flanking region, to one flanking region for each segment listed, or to only some of the flanking regions (Office Action, page 4). Applicant would like to clarify that the primers selectively hybridize to one flanking region for each segment listed. As such, the first term “each of” in claim 1, and dependant claims therein, has been amended to read “one of the.”

Accordingly, withdrawal of rejection of claims 1-4, 16 and 19 under 35 U.S.C. §112, second paragraph is respectfully requested.

#### **B. Rejection of claims 20-24**

According to the Office Action (page 5), “[c]laims 20-24 are indefinite over the recitation ‘and is about 90% complementary to at least nucleotide 3335 and 3337 of a PKD1 polynucleotide as set forth in SEQ ID NO.:1.’” The Examiner stated that the “language is very

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confusing because it is not clear what applicant intends by reciting ‘at least 90% complementary’ to the nucleotide.” Claims 20-24 have been cancelled herein, therefore the rejection is moot.

**IV. Rejections under 35 U.S.C. §102**

The following claims are rejected for allegedly being anticipated by the cited references discussed in detail below. Applicants respectfully traverse these rejections as they apply to the pending claims and for the reasons below.

**A. Rejection of claims 20, 21 and 22**

According to the Office Action, claims 20, 21, and 22 are allegedly anticipated by Gonczol et al. (WO 97/40165). Without acquiescing to the reasoning offered by the Office Action, in order to expedite prosecution toward allowance, Applicants have cancelled claims 20-22 herein, thereby rendering the rejection moot.

**B. Rejection of claims 20, 23 and 24**

According to the Office Action, claims 20, 23, and 24 are allegedly anticipated by Brennan (US 5474796). Without acquiescing to the reasoning offered by the Office Action, in order to expedite prosecution toward allowance, Applicants have cancelled claims 20, 23 and 24 herein, thereby rendering the rejection moot.

**C. Rejection of claims 20, 23, and 24**

According to the Office Action, claims 20, 23 and 24 are allegedly anticipated by Chee et al. (US 5837832). Without acquiescing to the reasoning offered by the Office Action, in order to expedite prosecution toward allowance, Applicants have cancelled claims 20, 23 and 24, thereby rendering the rejection moot.

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**V. Rejections under 35 U.S.C. §112, First Paragraph (written description)**

The following claims are rejected for allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse these rejections as they apply to the pending claims and for the reasons below.

**A. Rejection of claims 1-4, 16 and 19**

According to the Office Action, claims 1-4, 16 and 19 are rejected for various reasons, including that “with the exception of a single primer, SEQ ID NO:3, the claim requires primers that are not structurally defined in the claim, only defined as to their function.”

Without acquiescing to the reasoning offered by the Office Action, in order to expedite prosecution toward allowance, independent claim 1 has been amended to include the limitation of a primer with SEQ ID NO: 3 in the first amplification product. Claim 1 was also amended to remove references to the other primers and to remove references to PKD1 homologs.

With regard to the rejection of claims 3-4, 16 and 19, because each of these claims depend from independent claim 1, it is respectfully submitted that since a rejection based on 35 U.S.C. §112 cannot be maintained with respect to the independent claim, it follows that a rejection of the dependent claims cannot be maintained. Accordingly, withdrawal of rejection of claims 1-4, 16 and 19 under 35 U.S.C. §112, first paragraph is respectfully requested.

**B. Rejection of claims 20-24**

According to the Office Action, the Examiner stated that the “requirement that the claimed polynucleotides is 90% complementary to two nucleotides is still very broad in nature, leaving the identity of eight nucleotides plus any additional nucleotides open.” Without acquiescing to the reasoning offered by the Office Action, in order to expedite prosecution

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toward allowance, Applicants have cancelled claims 20-24 herein, thereby rendering the rejection moot.

**VI. Rejections under 35 U.S.C. §112, First Paragraph (enablement)**

The following claims are rejected for allegedly not enabling any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Applicants respectfully traverse these rejections as they apply to the pending claims and for the reasons below.

**A. Rejection of claims 1-4, 16 and 19**

According to the Office Action, claims 1-4, 16 and 19 are rejected “because the specification, while being enabling for primers having SEQ ID NO: 3, 5, 8, 10, 11, 14, 16, and 17, which can be used to specifically amplify PKD1 gene having SEQ ID NO: 1 and no PKD1 gene homologs, does not reasonably provide enablement for additional primers that have this property.”

Without acquiescing to the reasoning offered by the Office Action, in order to expedite prosecution toward allowance, independent claim 1 has been amended to include the limitation of a primer with SEQ ID NO: 3 in the first amplification product. Claim 1 was also amended to remove references to the other primers and to remove references to PKD1 homologs.

With regard to the rejection of claims 3-4, 16 and 19, because each of these claims depend from independent claim 1, it is respectfully submitted that since a rejection based on 35 U.S.C. §112 cannot be maintained with respect to the independent claim, it follows that a rejection of the dependent claims cannot be maintained. Accordingly, withdrawal of rejection of claims 1-4, 16 and 19 under 35 U.S.C. §112, first paragraph is respectfully requested.

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**B. Rejection of claims 20-24, 28-37, 39-42, 44, 46-52, 55-61, and 76-78**

Claims 20-24, 28-37, 39-42, 44, 46-52, 55-61, and 76-78 are rejected for allegedly not complying with the enablement requirement. The rejection is moot with regards to claims 20-24, as they have been canceled. In a telephone call to the Examiner on January 14, 2008, Applicants clarified that claim 25 was rejected under 35 U.S.C. §112, first paragraph. Applicants respectfully traverse the rejection as it applies to the pending claims.

Without acquiescing to the reasoning offered by the Office Action, in order to expedite prosecution toward allowance, independent claim 25, 44, and 60 have been amended to include the limitation of a primer with SEQ ID NO: 3 in the first amplification product. Claim 25, 44, and 60 were also amended to remove references to the other primers and to remove references to PKD1 homologs.

The Examiner also alleged that Claim 25 and associated dependent claims do not recite an association with a disease, as the specification does not set forth the relationship between the deletion at nucleotide 3336 and any PKD1 related disorder. Claim 25 has been amended herein to clarify that the presence of a mutation is indicative of a PKD1-associated disorder. Support for this amendment is found in paragraph [0147], which describes the association of a mutant PKD1 polynucleotide, for example the deletion at nucleotide 3336, with a PKD1-associated disorder.

In view of the above amendments, withdrawal of rejection of claims 25, 28-37, 39-42, 44, 46-52, 55-61, and 76-78 under 35 U.S.C. §112, first paragraph is respectfully requested.

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**Conclusion**

In view of the amendments and above remarks, it is submitted that the claims are in condition for allowance, and a notice to that effect is respectfully requested. The Examiner is invited to contact Applicant's undersigned representative if there are any questions relating to this application.

No fee is deemed necessary with the filing of this paper. However if any fees are due, the Commissioner is hereby authorized to charge any fees, or make any credits, to Deposit Account No. 07-1896 referencing the above-identified attorney docket number.

Respectfully submitted,



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